Remarks

Claims 23-39 are pending. Claim 23 has been amended. New claims 36 -39 have been added. Claims 26-28 and 30-32 have been withdrawn from consideration as being drawn to a non-elected invention. Pages 23, 32 and 33 of the specification have been amended to correct an obvious error.

A copy of the International Search Report was mailed by Applicants on January 18, 2001 including copies of all cited documents. However, for the Examiner's convenience, Applicants resubmit a copy of the International Search Report mailed on November 24, 2000 in the corresponding PCT application PCT/US00/14578. In addition, Applicants supply a copy of the English abstract of European Patent No. 0 655 237, which was not considered by the Examiner.

Amendments to the claims

Claim 23 was amended to specify the manner in which the porous matrices are formed. The matrix is made by dissolving the drug in a volatile solvent to form a drug solution, adding at least one volatile salt, incorporating at least one wetting agent, and removing the volatile solvent and volatile salt to yield the porous matrix. Support for this amendment can be found in originally filed claims 3 and 5. New claims 36 and 37 depend from claim 23 and define the drug as a drug with low aqueous solubility. Support for claims 36 and 37 can be found in originally filed claims 2 and 7. New claims 38 and 39 depend from claim 23 and define the drug as a water soluble drug. Support for claims 38 and 39 can be found in originally filed claims 8 and 9.

Amendments to the specification

The specification has been amended to correct obvious errors. Pages 23, 32 and 33 of the specification have been amended to replace the term "internal surface area" with "total surface area". In Example 17, the specification teaches that BET analysis was used to obtain the surface area measurements for the drug matrices produced in Examples 15 and 16 (see page 32, lines 23-26). As described in the specification at page 6, lines 12-13 and in the attached printouts, when BET is used to measure surface area, the resulting measurement is the total surface area of the microparticle. Therefore, the specification has been amended to correct obvious errors by replacing references to measuring internal surface area with references to measuring total surface area.

Rejection Under 35 U.S.C. § 102

Claims 23-25, 29, and 33-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,942, 253 to Gombotz *et al.* ("Gombotz"). Claims 23-25, 29, and 33-35 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,423,345 to Bernstein et al. ("Bernstein") Applicants respectfully traverse these rejections to the extent that it is applied to the claims as amended.

The Claimed Methods

The claims, as amended, are directed to methods for administering a drug to a patient. The drug is in a formulation which contains porous matrices which contain a wetting agent and microparticles of drug. The matrices are formed by dissolving the drug in a volatile solvent to

form a drug solution, adding at least one volatile salt, incorporating at least one wetting agent, and removing the volatile solvent and volatile salt. The resulting matrices are in the form of a dry powder and have a TAP density that is less than or equal to 1.0 g/mL and/or a total surface area that is greater than or equal to 0.2 m^2/g.

The porous drug matrices defined by the claims dissolve more rapidly than matrices which are formed without a volatile salt and a wetting agent. These results are demonstrated by the Examples and Figures in the specification. Figure 6, which was cited by the Examiner, shows that drug matrices which were formed with a wetting agent have much faster release than matrices that only contain the drug. Further, Figure 6 shows that drug matrices that are formed with both a wetting agent and a pore former, result in the fastest release of drug.

Example 18 refers to a drug matrix that only contains drug (i.e. does not contain a wetting agent). Example 15 A refers to a drug matrix that contains drug along with a wetting agent. Example 15B refers to a drug matrix that contains drug and a wetting agent and was formed using a volatile pore former.

After 20 minutes, about 70% of the drug matrix for Example 15A and about 90% of the drug matrix for Example 15B had dissolved. In contrast, after about 20 minutes, only 38% of Example 18 had dissolved. At 1 hour, about 100% of the drug matrices for Examples 15A and 15 B had dissolved, while only 64% of the matrix for Example 18 had dissolved. Thus, contrary to the Examiner's assertion, Figure 6 demonstrates that matrices that contain a wetting agent dissolve much more quickly than a matrix without a wetting agent. Further, drug matrices

formed using the method defined by claim 23, dissolve more quickly than matrices with only a wetting agent.

Gombotz

Gombotz does not teach every element of the claimed compositions. For example, Gombotz does not disclose using a volatile salt as a pore former to make the matrices, as required by the amended claims. Gombotz describes the pore formers as "water soluble compounds such as inorganic salts or sugars". (col. 9, lines 52-54) Further, nowhere does Gombotz disclose the formation of a porous matrix with a large total surface area and low TAP density, as required by the claims. Therefore, claims 23-25, 29, and 33-35, as amended, and new claims 36-39, which depend from claim 23, are novel in view of Gombotz.

Gombotz does not teach the inclusion of drugs with low aqueous solubility, as defined by claims 36 and 37. Gombotz is limited to matrices containing GM-CSF (see e.g. col. 2, lines 16-17 and col. 7, lines 4-29). Further, Gombotz does not disclose any of the drugs listed in claims 37 and 39. Therefore, claims 36, 37, and 39 are novel in view of Gombotz.

Bernstein

35 U.S.C. § 102(e) precludes a patent when the "invention was described in a patent granted on an application for patent *by another* filed in the United States before the invention thereof by the applicant." (emphasis added) U.S. Patent No. 6,423,345 to Bernstein et al. (the '345 patent) has four inventors, all of whom are named as inventors in the pending application. Therefore, any disclosure in the '345 patent is a disclosure made by the inventors of the pending

claims and could not be a disclosure "by another". Thus, the '345 patent is not prior art under 35 U.S.C. § 102 (e).

Allowance of claims 23-39, as amended, is respectfully solicited.

Respectfully submitted,

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I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail, in an envelope addressed to the Assistant Commissioner for Patents, U.S. Patent and Trademark Office, Alexandria, VA 22313-1450.

Pam Turnbough

Date: June 23, 2003